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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAKH, YELENA G	
ART UNIT	PAPER NUMBER
1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,194	POTYRAILO ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on 02/05/07 is acknowledged. Claims 25-50 are pending in the application.

Response to Amendment

2. The examiner sustains all rejections established in the previous Office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 25-50 are rejected under 35 U.S.C. 112, second paragraph,

It is not apparent, as to which specific "spatial distribution" is recited in the preamble of claims 25, 29 and 46? Where is the chemical species distributed? It is also not clear, what might be "*at least* a chemical species"? Was it meant to be "at least *one* chemical species", according to the Summary of the Invention?

It is further not apparent as to how the steps (4) and (5) are performed, since they appear to require a control of the process that needs a specific design of the apparatus, which was not disclosed in the specification.

It is not clear, what does it mean, "measuring a time at which said characteristic is detected" recited in step (7)? What time is meant here? Is it the time that a watch shows?

In step (8) it is not clear, what is a "spatial distribution of said interaction within said capillary"? The expression, "spatial distribution of the interaction", does not appear to be technically correct. Is this a distribution of the product of a reaction between the analyte and the reagent? Also, it is not clear, how is such spatial distribution obtained? Is it caused by the diffusion of the reaction product through the capillary?

The language of claims 25, 29 and 46 renders them and all dependent claims unclear and indefinite.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. **Claims 25-39, 46 and 48-50** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess (US 5,434,084).

Burgess discloses an apparatus and method for detecting a presence, determining a location, and quantifying an amount of chemical analytes, comprising providing a capillary with a permeable wall (8) to the analytes, delivering a fluid comprising a reagent, which is capable to selectively interact with analytes (col. 2, lines 63-68), into the capillary, and transferring a content of the capillary to an optical detector (Figure 1, col. 5, lines 50-56 and col. 6, lines 10-15), with the detector employing various optical methods. In one embodiment the optical methods utilized are UV, visible light or IR spectroscopy (col. 3, lines 47-49). In another embodiment the optical methods are scattering and/or reflective index measurements (col. 4, lines 54-60). See also col. 5, lines 17-20: "the device is compatible with numerous spectroscopic techniques including, but not limited to, absorbance, luminescence, chemiluminescence, fluorescence and light scattering for the analyte modulation of the optical signal". The concentration of the analyte is determined from the response of the optical detector. The permeable wall of the capillary comprises materials selected from "rubber, porous polypropylene, such as Celgard X-20 or X-10, and porous teflon. Each of the semipermeable membranes has pore sizes that control the movement of molecules based on the size of the molecules. For example, the pore size may range from about **0.05 μm** [50 nm] to about **10 μm**. The permeable membrane may also be an ion exchange membrane to separate analytes by size and charge. More specifically, anion exchange membranes include aminated polystyrene, divinyl benzene, aminated polypropylene, aminated polyethylene, other aminated polymers and other polymers with functional groups, such as trimethyl amine, ethyl dimethyl amine, and dimethyl ethanol amine. Cation exchange membranes include Nafion.RTM., and sulfonated polystyrene, polyacrylates and polypropylene. The ion exchange membrane can also comprise radiation grafted polymers such as polypropylene, polyethylene, and polystyrene, with various charged functional groups. The choice of the semipermeable or ion exchange membrane

depends upon the molecular size and charge characteristics of the analyte or analytes to be detected" (col. 7, line 68 and col. 8, lines 1-22). In one embodiment, Figure 4, "**a frit** [porous glass or ceramics] may be employed to prevent plugging of the sample capillary" (col. 12, lines 60-62), which corresponds to the subject matter of claims 9 and 10. Optical fibers are selected according to the application. "Fibers are available that cover most of the spectral region of the electromagnetic radiation spectrum from the **ultraviolet (220 nm) to the near-infrared**", which is in the range recited in claims 7 and 23 (col. 7, lines 17-20). "Microporous hollow fiber membranes [capillaries] were made of polypropylene and had **400 μm** [0.4 mm] internal diameters [claims 13 and 14], **0.03 μm** [30 nm] average pore size [claims 11 and 12], 40% porosity and **25 μm** wall thickness [claims 15 ad 16] (Hoechst Celanese, Charlotte, N.C., Model Celgard X-20) (Example 1, col. 13, lines 49-54). Burgess emphasizes, "by continuously renewing the reagent in the probe, the response and recovery times are improved over static reagent sensors. The reagent flow in mixing within the probe, creates a steep gradient in the chemical potential of the analyte across the permeable membrane interface, which results in a rapid steady state concentration" (col. 9, lines 3-5) and "the inventive flow optrode can adjust the sensitivity and dynamic range to the concentration of the analyte or changes in concentration of the analyte by varying the flow rate, the reagent composition, or by **operating in a stop flow mode**. Therefore, the inventive device and the inventive method for using the inventive device offer significant advantages over previously developed optrodes" (col. 10, lines 19-26). The probe is capable of being used in different environment, including soil or during combinatorial synthesis. Detecting any analyte with any analytical instrument connected to a computer inherently comprises stamping the time of the detection. Therefore, the step of measuring the time at which detection takes place is inherent for any analytical measurement, including Burgess method.

While Burgess does not specifically teach a method for determining location of the chemical species at the ground, it would have been obvious for any person of ordinary skill in the art to apply Burgess' method for detecting the chemical species in the soil and defining their location by using reference chemical species in this location.

7. **Claims 40-45 and 47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess in view of abundant prior art, e.g. Miller et al. (US 4,666,672), Klainer et al. (US

5,059,790), Tabacco et al. (US 5,268,972), Mohr et al. (EP 928,966 A1), Donner et al. (ACS Symposium), Bakaltcheva et al. (Anal. Chim. Acta), Sano et al. (Anal. Sic.), Gladilovich et al. (Zh. Anal. Khimii).

While Burgess does not specifically disclose analytes (chemical species) recited in the claims indicated above, he repeatedly emphasizes that any analytes, which can chemically react with the reagents "to create a reaction product that modulates electromagnetic radiation differently from the unreacted reagent" (col. 2, lines 63-67, col. 4, lines 64-69 and col. 7, lines 1-9)) are potential analytes for the apparatus disclosed. Moreover, he mentions that "the probe has multiple analyte capability because the same probe can be used for a variety of different analytes simply by changing the nature and/or concentration of the reagent in the reservoir" (col. 5, lines 23-28).

Miller discloses optrode for detecting halogenated hydrocarbons, including "chloroform, methylchloroform, sym-tetrachloroform, phenylchloroform, carbon tetrachloride, dichloro-methane, trichloroethylene, 1,1,2-trichloroethane and the like" (col. 4, lines 58-62).

Klainer discloses reservoir fiber optic chemical sensors for detecting various analytes, including trichloroethylene (TCE) (col. 6, line 51).

Tabacco discloses "aromatic hydrocarbon optrodes for groundwater monitoring applications", including detecting aromatic compounds, such as benzene, toluene (PhMe), ethylbenzene and xylene (col. 3, lines 50-52).

Mohr teaches detecting cycloaliphatic, primary, secondary or tertiary aliphatic and aromatic amines, including pyridine and aniline, by fluorescence chemical sensors (Abstract, page 2, par. [0012], Tables 1-3, pages 14, 15, 16).

Donner and Bakaltcheva disclose "multi-analyte explosive detection using a fiber optic biosensor", including detecting trinitrobenzole (TNT) (Abstract).

Sano teaches "fluorometric determination of aromatic aldehydes with 1,4-dimethyl-3-carbamoylpyridinium chloride", including detection of benzaldehyde, furfural and 4-methoxybenzaldehyde (Abstract).

Gladilovich teaches "fluorometric determination of aromatic aldehydes with 1,2-diaminobenzene", including detection of banzaldehyde and its derivatives (Abstract).

It would have been obvious for anyone of ordinary skills in the art to modify Burgess' apparatus for detecting analytes recited in claims 17-22, 24, because, as numerous references demonstrate these are important chemicals for analysis (toxins, explosives, etc.), which are conventionally analysed by optical methods, i.e. with conventional optrodes (halogenated hydrocarbons, polynitroaromatic hydrocarbons, mono-substitututed benzene, pyridine), as disclosed by Miller, Klainer, Tabacco, Mohr, Donner and Bakaltcheva, or fluorometrically by reacting with reagents which give specific optical characteristics, as taught by Sano and Gladilovich, while Burgess indicated the advantages of his apparatus versus conventional optrodes and standard fluorescence methods.

Response to Arguments

8. Applicant's arguments filed 02/05/07 have been fully considered but they are not persuasive. The amendment does not resolve most of the issues raised by the examiner in the previous Office action.

Regarding the term "spatial distribution", the examiner does not question the term itself, but its meaning in the context of the claims. It is unclear, which space is meant by this term – the space within the capillary, the space around the capillary? Is this the environment around the capillary? Since the nature of the chemical species is not clear and definite, it is unclear, as to where these species can be spatially distributed.

Regarding the expression "at least a chemical species", the expression is not equivalent to the expression "at least one chemical species". It can be interpreted as "chemical species" *vs.* "physical species", or "biological species". Why "at least chemical species" should refer to the plurality of chemical species, rather than their origin? The examiner considers the term unclear and indefinite; if the Applicants interpret it as "at least one chemical species", it is not apparent, as to why it cannot be amended this way.

Steps 4) and 5) are rejected under 35 U.S.C. 112, second paragraph, since their recitation is not clear and definite. If it were clear, how these steps should be performed then they might have been rejected under enablement requirements. However, from the claims the way they are written it is not apparent, as to how these steps are performed. It is not apparent, whether the

fluid medium is first stopped to allow the species to penetrate through the well, and then moved through the capillary. If this is the case, then the enablement requirements can be applied to the steps. However, it is the examiner's interpretation of the claims, rather than their language. Before applying enablement requirements the examiner first needs to understand, what actually is being recited in the claims.

Regarding measurement of the time, it is well known that the term has two meanings – a time period, and actual time shown by a clock (or watch, or any device listed by the Applicants). It is difficult to understand from the claim, why the time at which the species are detected should be measured. Would it be different, if the species were detected at noon or at 3 pm? The step does not make much sense. If the time *period* were meant to be measured between some reference time and the time when the species are detected – it may be reflected somehow the spatial distribution between the species, which are measured at different times. However, this is not what is being recited in the claims.

Repeating the term "spatial distribution" in step 8 confirms non-clarity and indefiniteness of the term, which the examiner indicated previously. If claim 8 recites "spatial distribution" of the product within the capillary, then which "spatial distribution" is meant in the preamble of the claims? Is this the same "spatial distribution", or this is a different "spatial distribution"? Should the "spatial distribution" of the product within the capillary reflect the spatial distribution of the chemical species somewhere outside the capillary? How can these two "spatial distributions" correlate with each other, if the speed of the flow of the chemical products in the fluid medium within the capillary can be totally different from that of the flow of the chemical species in the space outside the capillary? The "spaces" within the capillary and outside the capillary are not the same.

Regarding rejection over the prior art, the Applicants interpret the subject matter of their claims as the method for determining "a spatial distribution of a chemical species by measuring a time of the interaction between the reagent and the chemical species". The examiner would like to indicate, first, that the spatial distribution is just one of three possible parameters measured by the method and indicated in the preamble of the claims, with the presence and/or amount of the chemical species being two others. Second, the claims do not recite measuring "a time of the interaction between the reagent and the chemical species". Third, the examiner does not

understand, what this time might be, and how it is being measured. It seems that the Applicants misinterpret their own disclosure, since nowhere did the examiner found such measurement of the time of the interaction between the reagent and the chemical species. Such measurement would be closer to determining the rate of the reaction between the chemical species and the reagent, which does not appear to be the subject matter of the instant disclosure.

Moreover, detecting any analyte with any analytical instrument connected to a computer inherently comprises stamping the time of the detection. Therefore, the step of measuring the time at which detection takes place is inherent for any analytical measurement, including Burgess method.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

03/20/07

YELENA GAKH
PRIMARY EXAMINER